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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/562,191 | 10/26/2006 | Vega Mesignani | PP020667.0003 | 4113 |
| 27476 | 7590 | 07/07/2010 | EXAMINER | |
| NOVARTIS VACCINES AND DIAGNOSTICS INC. INTELLECTUAL PROPERTY- X100B P.O. BOX 8097 Emeryville, CA 94662-8097 | | | FORD, VANESSA L | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1645 | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 07/07/2010 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | |
|------------------------------|---|--------------------------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 10/562,191 Examiner VANESSA L. FORD | MASIGNANI ET AL. Art Unit 1645 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 14 April 2010.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-6, 10, 13, 18, 19, 21 and 22 is/are pending in the application.
 4a) Of the above claim(s) 13, 21 and 22 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-6, 10, 18 and 19 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 22 December 2005 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

1. Applicant's replacement drawings and response filed April 14, 2010 are acknowledged. Claims 7-9, 11-12, 14-17, 20 and 23 have been canceled.

Claims 13 and 21-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on March 23, 2009.

Claims 1-6, 10 and 18-19 are under examination.

A new Non-Final action is set forth below.

Objections/Rejections Withdrawn

2. In view of Applicant's amendment and response the following rejections have been withdrawn:

- a) objection to the specification, page 2, paragraph 2.
- b) objection to the specification, page 2, paragraph 3.
- c) objection to the specification, page 2, paragraph 4.
- d) objection to the drawings, pages 3-4, paragraph 5.
- e) rejection of claims 1-6, 10 and 18-19 under 35 U.S.C. 112 first paragraph, pages 5-9, paragraph 6.
- f) rejection of claims 1-6, 10 and 18-19 under 35 U.S.C. 102(a), pages 9-10, paragraph 7.

g) rejection of claims 1-6, 10 and 18-19 under 35 U.S.C. 102(b), pages 10-11, paragraph 8.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-6, 10 and 18-19 rejected under 35 U.S.C. 102(a) as anticipated Arico et al (*WO 03/010194 A2 published February 6, 2003*).

Independent claim 1 is drawn to a isolated immunogenic polypeptide comprising one or more of: (a) an amino acid sequence selected from the group consisting of SEQ ID Nos. 51, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18 and 54; (b) an amino acid sequence having at least 70% identity to a sequence as defined in (a); and/or (c) an amino acid sequence comprising a fragment of at least 8 consecutive amino acids of a sequence as defined in (a).

Independent claim 5 is drawn to an isolated immunogenic polypeptide of the formula NH₂ A{-X-L}_x-B-COOH.

Independent claim 6 is drawn to an isolated immunogenic polypeptide comprising the amino acid sequence -A-W₁-W₂-W₃-W₄-B.

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Arico et al teach a polypeptide that comprising an amino acid sequence comprising a fragment of at least 8 consecutive amino acids of a sequence as defined in (a). (e.g. SEQ ID No:51). Arico et al teach NAdA adhesins A protein from *Neisseria meningitidis* (see the Abstract). Arico et al teaches immunogenic compositions that comprises the polypeptides of the invention (pages 15-18). See the sequence alignment below. The at least 8 consecutive amino acids of a sequence in SEQ ID NO.51 (elected sequence) are underlined below.

```

Query Match           33.0%;  Score 422.5;  DB 1;  Length 355;

Best Local Similarity 38.7%;
Matches 103;  Conservative 45;  Mismatches 87;  Indels 31;  Gaps 7;

Qy      18 TTVSNYALAAQAQAQVKKDELSELKKQVKEMDAIDGI-----LDDNIAYEAE---- 66
        |   |       | : : : | : | :: : |||:|       | :||   ||
Db      94 TKTVNENKQNVDAKVKAEESEIEKLTTKLADTDATTNALNKGGENITTFAEETKTN
153

Qy      67 ---VDAKL-----DQHSAALGRHTNRLNNLKTIKEAKGDSSEALDKIEALEEQNDEF
116
        :| ||       |:|:| |       :| :|   | |::|   ::|| |   ::| |
Db      154 IVKIDEKLEAVADTVDKHAEAFNDIADSLDETNTKADEAVKTANEAKQTAETKQNVD--
211

Qy      117 LADITALEEGVDGLDDITGIQDNISD---IEDDINQNSADIATNTAAIAHTQRLDNL
172
        | : | |       | : | : | : |       : : | ||||| | | | :: |:|:
Db      212 -AKVKAETAAGTANTAADKAEAVAAKVTDIKADIATNKADIAKNSARIDS
269

Qy      173 DNRVNNLNKDLKRGAAQALNGLFQPYNVGKLNLTAAVGGYKSQTAVAVGTGYRNYENI
232
        | | | | |: ::||| | |||:||| | | |: |: |||:|||: |: | |
Db      270 DKNVANLRKETRQGLAEQAALSGLFQPYNVGRFNVTAAVGGYKSESAVAIGTGFRFTENF
329

Qy      233 AAKAGVAF--THGGSATYNGVNF EW 256
        ||||||| : | | | |: |||:|||
Db      330 AAKAGVAFVGTSSGSSAAYHGVNYEW 355

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Arico et al anticipate claimed invention.

4. Claims 1-6, 10 and 18-19 rejected under 35 U.S.C. 102(b) as anticipated Fraser et al (*WO 99/57280 A2 published November 11, 1999*).

Independent claim 1 is drawn to a isolated immunogenic polypeptide comprising one or more of: (a) an amino acid sequence selected from the group consisting of SEQ ID Nos. 51, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, 15, 16, 17, 18 and 54; (b) an amino acid sequence having at least 70% identity to a sequence as defined in (a); and/or (c) an amino acid sequence comprising a fragment of at least 8 consecutive amino acids of a sequence as defined in (a).

Independent claim 5 is drawn to an isolated immunogenic polypeptide of the formula NH₂ A-{X-L}_x-B-COOH.

Independent claim 6 is drawn to an isolated immunogenic polypeptide comprising the amino acid sequence -A-W₁-W₂-W₃-W₄-B.

Fraser et al teach polypeptides comprising Neisserial polypeptides (see the Abstract). Fraser et al teaches immunogenic compositions that comprises the polypeptides of the invention (pages 33-36). See the sequence alignment below. The at least 8 consecutive amino acids of a sequence in SEQ ID NO.51 (elected sequence) are underlined below.

Query Match 32.5%; Score 416; DB 1; Length 364;
Best Local Similarity 38.1%;
Matches 104; Conservative 45; Mismatches 86; Indels 38; Gaps 8;

Qy 18 TTVSNYALAAQAQAAQVKKDELSELKKQVKEMDAAI---DGILD-----DNIAYE 64
Db 96 TKTVNENKQNVDAKVKAEESEIEKLTTKLADTDAALADTDALDETTNALNKLGENITTF
155

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| | |
|-----------|---|
| Qy 109 | 65 AE-----VDAKL-----DQHSAALGRHTNRLNNLKTIAEKAGDSSEALDKIEAL |
| | : : : : : : : : : : |
| Db 215 | 156 AEETKTNIVKIDEKLEAVADTVDKHAEAFNDIADSLDETNTKADEAVKTANEAKQTAEET |
| | |
| Qy 165 | 110 EEQNDEF LADITALEEGVDGLDDITGIQDNISD ---IEDDINQNSADIATNTAAIATH |
| | :: : : : : : : : : : : : : |
| Db 271 | 216 KQNVD---AKVKAETAAGTANTAADKAEAVA AKVT DIKADIATNKADI AKN |
| | |
| Qy 225 | 166 TQR LDNL DNRVNNLNKDLKRG LAQA ALNGLF QPY NVGKLNLTAAVGGYKSQTA AV AVGTG |
| | : : : : : : : : : : : |
| Db 331 | 272 SARIDS LDKN VANLRKETRQGLAEQAALS <u>GLFQPY</u> NVGRFNV <u>TAAVGGYK</u> S E AVAIGTG |
| | |
| Qy | 226 YRYNENIAAKAGVAF--THGGSATYNGVNF EW 256 |
| | : : : : : |
| Db | 332 FRFTENFAAKAGVAVGTSSGSSAAYHVGVN YEW 364 |
| | |

Status of Claims

- #### **5. No claims allowed.**

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANESSA L. FORD whose telephone number is (571)272-0857. The examiner can normally be reached on 9 am- 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0756. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vanessa L. Ford/
Primary Examiner, Art Unit 1645
June 29, 2010